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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,243	02/01/2000	Andras Konya	UTKO.002	5915

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EXAMINER


THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/496,243	Applicant(s) HYODOH ET AL. 	
	Examiner Michael Thaler	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) 37-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-27, 29-33, 35, 36, 67-86, 88-105, 107 and 108 is/are rejected.
- 7) ☒ Claim(s) 17, 28, 34, 87 and 106 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 37-66 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 14.

Claims 1-16, 18-27, 29-33, 35, 36, 67, 68, 71-86, 88-105, 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallsten (4,655,771) in view of Sandock (5,800,519). Wallsten discloses a plurality of shape memory wires (2, 3 etc.) woven together and crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides (figure 1a). Wallsten fails to disclose both ends of at least one shape memory wire being located proximate one end of the body. However, Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end (col. 5, lines 22-55). This arrangement has the apparent advantage of reducing the number of free ends on the wires, which free ends could damage the blood vessel during stent insertion. It would have been obvious to locate both ends of each Wallsten wire at one end of the body and provide a bend

in the wire at the opposite end of the body so that it too would have this advantage. As to claim 2, Wallsten fails to disclose nitinol. However, Sandock teaches that stent wires should be made of nitinol in order to make the stent very elastic (col. 6, lines 25-26). It would have been obvious to make the Wallsten stent wires nitinol so that it too would have this advantage. As to claim 5, Wallsten fails to disclose the claimed wire diameter. However, Sandock teaches that stent wires should be of a diameter within the claimed range apparently in order to make the stent very elastic (col. 6, lines 28-30). It would have been obvious to make the Wallsten stent wires of this diameter so that it too would have this advantage. As to claim 6, Wallsten fails to disclose the number of wires as at least 6. However, it is well known in this art to use at least 6 stent wires in order to enable the stent to be effective in large body vessels. It would have been obvious to use at least 6 stent wires in the Wallsten stent so that it too would have this advantage. As to claims 8 and 9, Wallsten fails to disclose a tapered or an hourglass shape. However, it is well known in this art to shape a stent in a tapered or an hourglass shape in order to enable the stent to be effective in body vessels having a variable diameter. It would have been obvious to shape the

Wallsten stent in a tapered or an hourglass shape so that it too would have this advantage. As to claim 12, note col. 11, lines 37-54 of Wallsten. As to claims 13-16, Wallsten fails to disclose the claimed graft materials. However, it was well known in this art to use the claimed materials as graft material since these materials are very biocompatible. It would have been obvious to use these materials in the Wallsten graft so that it too would have this advantage.

Claim 69 is rejected under 35 U.S.C. 102(e) as being anticipated by Hansen et al. (5,968,088) for the reasons set forth on page 6, lines 14-19 of the Office Action mailed Nov. 20, 2002.

Claims 69 and 70 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hansen et al. (5,968,088). As to claim 69, Hansen et al. disclose a shape memory wire having a first segment 10 and a second segment 11 separated by a bend 13 (Wires 10 and 11 are actually two portions of the same continuous wire as shown in figure 3 where wires 10 and 11 are shown merging together at eyelet 13. Further, the phrase "continue into each other" in col. 8, lines 33-34 indicate that wires 10 and 11 are continuous.), the segments being arranged to form loops and

twisted segments such that at least two contiguous substantially closed loops (one of the hart shaped loops shown in figure 4 and one of the loops formed by the top half of the twisted wires at the bottom of the hart shaped loop) are separated from another loop (the hart shaped loop below the twisting of the wires described above) by a twisted segment (the bottom half of the twisted wires described above). Alternatively, it would have been obvious that the twisting of the wires described above form substantially closed loops since the wires extend more than 360 degrees when twisted. As to claim 70, the segments are secured to each other in loop-defining locations (e.g. in figure 3, where the segments are twisted about each other just below eyelet 13 and where they are twisted about each other at 12), the segments also extending between the loop-defining locations in spaced relation to each other so as to form two loops (the loops formed by the segments 10, 11 helically winding around the longitudinal axis of the stent), the loops having a compressed shape (col. 2, line 23). Alternatively, it would have been obvious that first and second segments 10, 11 meet and are secured to each other at end 12 (or at an intermediate location along the stent) since they extend from eyelet 13 helically with a pitch such that they extend circumferentially one cell 2 as

they extend longitudinally to the next circumferential row of cells and since there can be only four cells in each circumferential row of cells (col. 9, lines 26-27) while there can be five circumferential rows of cells (figure 5).

Claims 17, 28, 34, 87 and 106 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive. As to claim 1, Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end. Thus, instead of forming a free end of each wire at end 18, Sandock teaches forming a bend at the wire. This arrangement has the advantage described above. It would have been obvious to include this feature into the Wallsten stent so that it too would have this advantage. As to claim 20, Wallsten clearly discloses "at least one strut", as claimed, which comprises, for example, a segment of one of the wires. As to claim 67, all of the Wallsten embodiments, and particularly the figure 8 embodiment, occludes (partially) the

body vessel. As to claim 68, the Wallsten segments (wires) alternate between being farther from the stent axis since they are woven as seen in figure 1a. As to claim 70, it would have been obvious that first and second segments 10, 11 of Hansen et al. meet and are secured to each other at end 12 (or at an intermediate location along the stent) since they extend from eyelet 13 helically with a pitch such that they extend circumferentially one cell 2 as they extend longitudinally to the next circumferential row of cells and since there are can be only four cells in each circumferential row of cells (col. 9, lines 26-27) while there can be five circumferential rows of cells (figure 5).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated

Application/Control Number: 09/496,243
Art Unit: 3731

Page 7


from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
9/8/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731